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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,014	CHU, WEI-SING	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70,72-75,77-79 and 92-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70,72-75,77-79 and 92-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 70, 72-74, 76, 92-96 is acknowledged and has been entered.

2. Applicant's addition of claims 98-104 is acknowledged and has been entered.

3. Applicant's cancellation of claim 97 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 70, 72-79 and 92-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 70 recites the limitation "a tissue sample" in the first, fifth, and sixth lines of the claim. There is insufficient antecedent basis for this limitation in the claim. In particular, it is unclear if these are all referring to the same tissue sample, rendering the claim unclear. This is also applicable to claim 98.

7. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 70, 72-79, 96 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al [US 5,639,423].

With respect to claim 70, Northrup et al teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer connected to an inductor (ultrasound transducer and generator) (column 7, lines 29-42) and a Lamb-wave sensor (first sensor) in a solution (column 12, lines 1-9) in a chamber (reaction chamber) (column 7, lines 29-35), where the transducer is located on a thin film wall of the chamber (claims 1, 3). Northrup et al further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52). Northrup et al also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (central processing unit) (column 4, lines 40-45). A tissue sample is disclosed at column 5, line 60). Northrup et al further teach that the reactor may be used to process fixed cells or tissues for PCR and subsequent techniques (column 5, lines 42-61) and therefore the solutions (reagents) in the chamber (column 7, lines 29-35) disclosed by Northrup et al. would be for processing or fixing. Furthermore, Northrup et al. teach that the device is immersed in solution (column 12, lines 1-9), and therefore the sample would also be immersed.

The limitations that "the central processing unit adjusts a frequency or an intensity of said ultrasound in response to signals from the first and second sensors to regulate the ultrasound generator and adjusts a frequency or intensity of ultrasound in response to the signals from the first and second sensors" and "the system causes the tissue sample to become fixed with no or minimal damage to the tissue sample" are regarded as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Since Northrup et al teach that the integrated microelectronic devices are capable of processing and storing detection signals so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45), the microlectronic devices would be capable of performing the function of the CPU.

10. With respect to claims 72-74, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency) using Lamb-wave sensors (column 11, lines 39-42). Northrup et al further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52).

11. With respect to claim 75, detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45).

12. With respect to claim 77-79, the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10), as well as a power in the range of 0.01-200 W/cm^2, as power is merely a function of energy over time.

13. With respect to claim 96, Northrup et al. teach pumps ((LW_1, LW_2, LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

14. With respect to claim 97, a used solution is pumped to a waste receptacle (column 7, lines 35-37 discloses a channel equipped with a pump, wherein the channel connects the reaction chamber with a detection chamber, which is considered the claimed waste receptacle.)

15. With respect to claim 98, Northrup et al teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer connected to an inductor (ultrasound transducer and generator) (column 7, lines 29-42) and a Lamb-wave sensor (first sensor) in a solution (column 12, lines 1-9) in a chamber (reaction chamber) (column 7, lines 29-35), where the transducer is located on a thin film wall of the chamber (claims 1, 3). Northrup et al further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48). Northrup et al also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or

by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (central processing unit) (column 4, lines 40-45). A tissue sample is disclosed at column 5, line 60). Norhtrup et al further teach that the reactor may be used to process fixed cells or tissues for PCR and subsequent techniques (column 5, lines 42-61) and therefore the solutions (reagents) in the chamber (column 7, lines 29-35) disclosed by Northrup et al. would be for processing or fixing. Furthermore, Northrup et al. teach that the device is immersed in solution (column 12, lines 1-9), and therefore the sample would also be immersed. The transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10), as well as a power in the range of 0.01-200 W/cm^2, as power is merely a function of energy over time.

The limitations that "the central processing unit adjusts a frequency or an intensity of said ultrasound in response to signals from the first and second sensors to regulate the ultrasound generator and adjusts a frequency or intensity of ultrasound in response to the signals from the first and second sensors" and "the system causes the tissue sample to become fixed with no or minimal damage to the tissue sample" are regarded as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Since Northrup et al teach that the integrated

microelectronic devices are capable of processing and storing detection signals so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45), the microlectronic devices would be capable of performing the function of the CPU.

16. With respect to claim 99, the transducer is further capable of producing Lamb waves with frequencies from 1to 200 MHz (column 11, lines 3-10).

17. With respect to claims 100-102, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency) using Lamb-wave sensors (column 11, lines 39-42). Northrup et al further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52).

18. With respect to claim 103, detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (column 4, lines 40-45).

19. With respect to claim 104, Northrup et al. teach pumps ((LW_1, LW_2, LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423], in view of Chu [5,958,341].

Northrup et al. teach the invention substantially as claimed (see above with respect to claim 70). Northrup et al. teach that the device can be used to process fixed cells as well as tissue samples (column 5, line 60). Therefore, the tissue in the reaction chamber of Northrup et al. would be immersed in a fixing solution (having already been fixed). However, Northrup et al. do not teach that the sample is immersed in a solution of 10% formalin, alcohol, xylene or parafin.

Chu teach preparing a tissue sample with 10% formalin embedded in paraffin and later treated with xylene and ethanol in order to fix the tissue (column 18, lines 5-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made for that the tissue samples would have been immersed in the solutions as taught by Chu in the Northrup et al. invention in order to be fixed, because Chu teach that these solutions are used in preparing tissue samples, particularly in fixing.

Response to Arguments

22. Applicant's arguments filed September 8, 2006 have been fully considered but they are not persuasive. In particular, applicant argues fixing tissue samples has not been disclosed as an use of the device of Northrup et al., and in fact that Northrup discloses the use of ultrasonic waves for disrupting and exposing cell components through lysis. The Office does not dispute

this fact. However, this does preclude the device of Northrup et al. from fixing or processing tissue samples. Since the device of Northrup et al. appears to fulfill all the structural limitations recited by applicant, it would appear to also be capable of fixing tissue samples. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masha*, 2 USPQ2d 1647 (1987).

23. Applicant claims a system for fixing and processing a tissue sample. However, it is noted that to one of ordinary skill in the art, the presence of ultrasound transducers is not a necessary element for fixing tissues, as all that is required is a fixing solution. How the product is used has no patentable weight in a product claim, as long as the product is capable of performing that function.

24. Furthermore, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

25. Applicant may wish to further clarify in the claims how the transducers of Northrup et al. differ in terms of structural or physical differences from the transducers claimed in the instant application, such that they would not be capable of fixing tissue.

Conclusion

26. No claims are allowed.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

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